Kraft Foods

J. Edward Thompson
Chief Food Law Counsel

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April 28, 2000

Docket No. 98-091-1
Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Proposed Rule; Administrative Practices and Procedures; Good Guidance Practices; Docket No. 99N-4783; 65 Fed. Reg. 7321 (Feb. 14, 2000)

Dear Sir or Madam:

Kraft Foods, Inc. welcomes this opportunity to comment on the above-referenced proposed rule. Kraft often relies upon the advice and guidance of the Food and Drug Administration in our efforts to ensure compliance with both the letter and the spirit of applicable law and regulations. Accordingly, the Company has a direct interest in FDA's procedures for preparing and implementing guidance documents.

Kraft recognizes the importance of establishing Good Guidance Practices (GGPs), and generally supports codification of the GGPs. The Company is concerned, however, that FDA may be unnecessarily detracting from the value of its guidance documents by failing to provide companies in compliance with FDA guidances with a safe harbor from regulatory action.

Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), although guidance documents are not legally "binding" on FDA, the agency must ensure that its employees do not deviate from such guidances without appropriate justification and supervisory concurrence. 1/ Moreover, although such documents do not technically create or confer any rights on any person, they are

1/ 21 U.S.C. § 371(h)(1)(A).

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supposed to present the agency's views on matters under FDA's jurisdiction. 2/ In short, FDAMA provides that a guidance document will represent FDA policy, and that the agency will act in keeping with a guidance document unless the agency can show that there is appropriate justification for deviation.

Kraft urges FDA to exercise its enforcement discretion and provide companies that adhere to FDA guidance documents with a safe harbor that protects them from enforcement action. Rather than take enforcement action inconsistent with a guidance document, Kraft recommends that, when faced with a situation in which there may be appropriate justification to deviate from a given guidance document, the agency be required to amend, or at a minimum, to publish a proposal to amend the guidance document itself prior to initiating an enforcement action. FDA should be able to articulate its new enforcement position and provide industry with notice through modification of the guidance document and permit the public, including the affected industry, the opportunity to comment on the new position or to implement the changes necessary to be in compliance with the new interpretation prior to being accused of a violation.

In addition, Kraft encourages FDA's development of an appeals mechanism, as required under FDAMA, 3/ to address complaints regarding FDA's development and use of guidance documents. However, the Company believes that the appeals mechanism, without the establishment of a safe harbor, would be insufficient to address concerns with actions taken by FDA that are inconsistent with its guidance documents.

If FDA takes the position that the guidance documents will not provide a safe harbor, then, at the very least, Kraft believes that compliance with an FDA guidance document should provide evidence of a company's intent to comply with agency regulations in any related enforcement proceeding. In all fairness, if a company adheres to the agency's own interpretation of its requirements, FDA should be willing to recognize the company's good faith effort to comply with the law consistent with the Agency's published interpretation. If guidance documents do not provide even this small amount of certainty, their usefulness to industry and the Agency is severely limited.

2/ 21 U.S.C. § 371(h)(1)(B).

3/ 21 U.S.C. § 371(h)(4).

It is especially important for FDA to promote the utility of informal guidances at a time when the agency is concerned about limited resources for formal rule-making procedures. FDA recently expressed this concern in its proposal to limit the agency's review of citizen's petitions to consider only those petitions related to food safety issues. If a guidance document does not provide a safe harbor for the regulated community, companies will continue to petition for formal rulemaking to ensure that they are in compliance – unnecessarily draining already limited resources.

Kraft appreciates this opportunity to comment and looks forward to working cooperatively with the agency in this most important area.

Sincerely,

J. Edward Thompson
Chief Food Law Counsel

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